A Prospective, Multi-Center Study of the IlluminOss® Photodynamic Bone Stabilization System for the Treatment of Impending and Actual Pathological Fractures in the Humerus from Metastatic Bone Disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON40648

Source
ToetsingOnline

Brief title
PBSS - Pathological Humerus Fractures

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
bone healing, upper arm fracture

Research involving
Human

Sponsors and support

Primary sponsor: IlluminOss Medical In.
Source(s) of monetary or material Support: IlluminOss Medical Inc.

Intervention

Keyword: fracture, humerus, pathological, stabilization

Outcome measures

Primary outcome

The primary study parameters is subject success which is determined by

achieving the safety and effectiveness endpoints at the Day 90 Visit.

Safety Success is evaluated by meeting all of the following criteria:

• Clinical

- No Serious Device Related Complications

- No additional surgical interventions (i.e.revisions,

supplements, fixations, or removals)

• Radiographic

- No device fracture, migrations, mal-alignment or loss of

reduction or fixation

Effectiveness Success is evaluated by achieving pain reduction and functional

improvement:

• Pain Reduction

- VAS Pain Score change of >= -33% compared to baseline

• Functional Improvement

- Barthel Index of Activities of Daily Living (ADLs)

improvement of >= +10% from baseline

- EORTC QLQ-C30 improvement of > +10% from baseline

- EORTC QLQ-BM22 improvement of > +10% from baseline

Secondary outcome

The secondary endpoints, evaluated at the Day 90 Visit, and at the Extended

Follow Up Visits include:

1. The seven composite endpoint components listed under the primary endpoint.

Other secondary endpoints include:

2. Duration of index procedure and length of hospital stay.

3. Activities of Daily Living score through all follow-up intervals.

4. VAS Pain score from baseline through all follow-up intervals.

5. Disability status.

6. Evaluation of duration of physical therapy prescription.

7. Assessment of prescription and over-the-counter analgesic medication use.

8. Survivability from time of index procedure to death.

The safety endpoints evaluated include:

1. Incidence and number of AEs.

2. Incidence and number of procedure- and device-related complications.

Study description

Background summary

Proximal humerus fracture is the second most common fracture of the upper extremity accounting for 5% of all fractures. The treatment objective in all humerus fractures is to facilitate healing of the bone and soft tissue in order to maximize function of the upper extremity while minimizing risk to the patient. An important factor in treatment procedures is fracture stabilization, as it allows for early range of motion. For most types of serious humerus fractures, casting is not a suitable way of treatment due to the location of the humerus. Those fractures are more likely to require surgical intervention, which mostly involves the use of a plate fixation system or intramedullary nail device. Although current techniques like these are effective in fracture reduction, they are associated with significant complications during surgical procedures and they may impact the ability of the patient to regain early mobility. In an attempt to overcome those negative side effects, the IlluminOss Photodynamic Bone Stabilization System (PBSS) was developed. The PBSS device, a balloon filled with a monomer, is inserted through a small percutaneous incision. Once in place and spanning the fracture, the balloon is infused with a light curable monomer causing the balloon to expand, thereby filling the medullary canal and providing longitudinal stability after the device has hardened out. Additional pins and screws are available for extra stabilization but in contrast to other available intramedullary bone pins, the location of those screws is not predetermined. This allows the surgeon to provide an optimal environment for normal biological healing to occur. The PBSS is CE-marked for treatment of fractures in the phalange, metacarpal, distal radius, radius, ulna, olecranon, clavicle and fibula since 2009. Its use has been associated with shorter operative times, and preserving blood and nerve pathways intra- and post-operatively. Furthermore, no procedural or intra-operative adverse device events have been reported to date when used for treatment of those CE-marked indications. Taken together, the minimal invasiveness, the longitudinal stability and the extra possibilities for stabilization are expected to decrease the negative side effects of current humerus fracture treatment techniques.

Study objective

The primary objective of the study is to collect safety and performance data of the IlluminOss Photodynamic Bone Stabilization System when used for the treatment of painful impending and actual fractures of the humerus secondary to metastatic malignancy.

Study design

This is a prospective, multi-center, open-label clinical study with the purpose of assessing performance of the PBSS in the treatment of impending and acutal fractures of the humerus. A maximum of 45 patients undergoing IlluminOss device implant are expected to be enrolled in the study.
Each patient enrolled in the study will be followed to 360 days post-index procedure. The following study visits will occur: Visit 1. Screening; visit 2. Surgery; Visit 3. 7 days post-op; Visit 4. 30 days post-op; Visit 5. 90 days post-op; Visit 6. 180 days post-op; Visit 7. 360 days post-op.

Intervention

- Medical device: IlluminOss Photodynamic Bone Stabilization System (PBSS)
- Surgery: Insertion of PBSS during surgical procedure performed in operating room under general anesthesia; the device uses an insertion catheter to deploy an inflatable, thin wall PET balloon into the medullary canal of the bone within the fracture site. The balloon is then infused with a light curable monomer which causes the balloon to expand and fill the medullary canal on either side of the fracture. The monomer filled balloon is then cured in-situ using a fiber optic light source resulting in a permanent non-active humeral implant.
- Questionnaires: Visual Analog pain Score (VAS), Barthel Index, EORTC QLQ-30 and QLQ-BM22.

Study burden and risks

During the study participation period of 360 days post-operative, patiënts have to perform seven hospital visits. The burden for participants of this study consists of those two extra hospital visits, the assessment of VAS, Barthel Index, EORTC QLQ-30 and QLQ-BM22 and additional radiographic assessments that may not be standard of care in the follow-up of traditional impending fracture treatment surgery. Enrolled subjects will have standard A/P, lateral and oblique radiographs taken at the Day 7, 30, 90, 180 and 360 assessments. The risk of exposure to extra radiation at these time points is expected to be less than that received during a routine airplane flight.
Furthermore, potential risks for participants include anticipated risks associated with any upper arm fracture, anesthesia and surgical treatment. Patients may benefit from participating in the study by having a shorter operative time to treat their fracture, having a shorter length of hospital stay, requiring fewer narcotic and physical therapy prescriptions, having fewer overall complications, and by regaining the use of their affected arm sooner than if they were treated with conventional humerus plates or IM rods. Patients may not experience benefits.
The results of this study will benefit the medical community treating impending pathological fractures secondary to metastatic bone disease by evaluating the safety and performance of the PBSS. The potential benefits of treatment with PBSS outweigh the potential risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

General inclusion criteria:
- Skeletally mature adult males and females 18 years of age or older
- Impending or actual pathological fracture of the humerus, secondary to metastatic bone disease
- Females: neither pregnant nor intending to become pregnant during the course of the study
- Able to understand and provide informed consent
- Willing and able to comply with post-operative treatment protocol and follow-up visit schedule;Impending Fracture-Specific Inclusion Criteria:
- Documented presence of solitary metastatic lesion.
- Mirels Criteria Score >= 8.
- Destruction of cortical bone at impending fracture site > 50%.;Actual Fracture-Specific Inclusion Criteria:

- Radiograph-confirmed diagnosis of acute, single isolated fracture of the humerus. AO classification 11A1, 11A2 and 11B1, 11B2 and 12A1,12A2 and 12B1, 12B2 and 13A1,13A2 and 13B1, 13B2.
- Fracture is closed, Gustilo Type I or IIA

Exclusion criteria

General Exclusion Criteria:
- Primary tumor (osteogenic origin, etc.) at site
- Impending fracture or actual fracture location other than humerus
- Current concomitant traumatic fracture of any other location
- Active or incompletely treated infections that could involve the device implant site
- Distant foci of infection that may spread to the implant site
- Allergy to implant materials or dental glue
- Vascular insufficiency, muscular atrophy, or neuromuscular disease at implant site
- Uncooperative patients, or patients who are incapable of following directions (for example, as a consequence of a neurological or psychiatric disorder);Impending Fracture-Specific Exclusion Criteria:
- Mirels Score < 8
- Destruction of cortical bone at impending fracture site < 50%
- Prior surgery and/or prior fracture of affected site
- Any articular component to impending fracture site;Actual Fracture-Specific Exclusion Criteria:
- Index treatment is greater than 28 days post fracture
- Open fractures with severe contamination
- Extremely comminuted fractures where insufficient holding power of the balloon on the intramedullary canal is probable
- Delivery sheath is unable to cross fracture site after proper fracture reduction and realignment
- Patients whose intramedullary canal at site of fracture measures smaller than the diameter of the sheath provided

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2015
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	IlluminOss Photodynamic Bone Stabilization System
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	21-11-2014
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	20-07-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49653.072.14

Study results

Date completed: 14-03-2016

Actual enrolment: 4

Summary results
Trial is onging in other countries